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UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES

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*Ex parte* GIJSBERTUS JOHANNES VAN OORSCHOT,  
EELKO GERBEN TER SCHURE, and ELKE A. TRAUTWEIN

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Appeal 2010-000964  
Application 10/072,570  
Technology Center 1600

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Decided: June 18, 2010

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Before ERIC GRIMES, DEMETRA J. MILLS, and  
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

McCOLLUM, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to a food product. The Examiner has rejected the claims as obvious. We have jurisdiction under 35 U.S.C. § 6(b). We reverse.

STATEMENT OF THE CASE

Claims 11-16, 19-24, and 27-29 are on appeal. Claims 1-9 are also pending but have been withdrawn from consideration by the Examiner.

(App. Br. 3.) We will focus on claim 19, the only independent claim on appeal, which reads as follows:

19. A food product selected from the group consisting of a margarine, a dressing, a sweet, a cereal bar, a breakfast cereal and a beverage, said food product comprising an extract of a fermentation product formed by fermenting a substrate comprising more than 50% by weight of soy ingredients with a statins producing *monascus ruber* fungus; wherein the fermentation product comprises one or more statins and one or more polyphenols and has a Hue a\* value less than 20; wherein said soy ingredients are selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes; and wherein said extract is an ethanol extract or an edible oil extract.

Claims 11-16, 19-21, 23, 24, 27, and 29 stand rejected under 35 U.S.C. § 103(a) as obvious over Manzoni 1999<sup>1</sup> in view of Zhang<sup>2</sup> and Chaihorsky<sup>3</sup> (Ans. 3).

Claims 22 and 28 stand rejected under 35 U.S.C. § 103(a) as obvious over Manzoni 1999 in view of Zhang, Chaihorsky, and Zilliken<sup>4</sup> (*id.* at 7).

The Examiner relies on Manzoni 1999 for teaching “a method of screening *Monascus* and *Aspergillus* strains for statins production” (*id.* at 5). Specifically, the Examiner finds that Manzoni 1999 teaches that “lovastatin is obtained from *M. ruber*” (*id.* at 8). The Examiner also finds that Manzoni 1999 teaches that statins decrease cholesterol (*id.* at 5). In addition, the Examiner finds that Manzoni 1999 teaches that the “medium contained 3% whole or defatted soybean flour” (*id.*). However, the

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<sup>1</sup> Matilde Manzoni et al., *Production of statins by filamentous fungi*, 21 BIOTECHNOLOGY LETTERS 253-257 (1999).

<sup>2</sup> Zhang et al., US 6,046,022, Apr. 4, 2000.

<sup>3</sup> Chaihorsky, US 5,670,632, Sep. 23, 1997.

<sup>4</sup> Zilliken, US 4,218,489, Aug. 19, 1980.

Examiner concludes that the claimed amounts of soy ingredients would have been obvious (*id.* at 5-6).

The Examiner relies on Zhang for teaching “a method of fermenting red rice with *Monascus* in order to formulate a dietary supplement or medicament for the treatment of high cholesterol in humans” (*id.* at 6). The Examiner finds that Zhang teaches that “*Mona[s]cus ruber* is taught as a possible strain used in the fermentation process” and that “soybeans may be fermented by the process in order to obtain a nitrogen source in the food product” (*id.*).

The Examiner relies on Chaihorsky for teaching that “isoflavones have been isolated from soybean plants for use as dietary supplements” and that “the isoflavones are eluted by a polar solvent such as methanol or ethanol” (*id.*). The Examiner concludes that it would have been obvious to combine the teachings of Manzoni 1999, Zhang, and Chaihorsky “to further include extracting the fermentation product with ethanol for a food product” (*id.*).

The Examiner relies on Zilliken for teaching vegetable oil, as recited in dependent claims 22 and 28 (*id.* at 8).

Appellants argue that “there is no teaching or suggestion in Manzoni [1999] about using more than 50% by weight of soy ingredients (e.g., crushed whole soybeans) as the fermentation medium, a level over 16 times higher than that taught [by] Manzoni [1999]” (App. Br. 13). Appellants also argue:

Zhang et al teaches a substrate containing over 50% rice and at most about 6.5% soy ingredients. There is no teaching or suggestion whatsoever in Manzoni [1999] or Zhang et al that

increasing the level of soy [flour] and in fact using soy [flour] as the principle component of the culture medium would have improved the low performance of *M rubber* [sic] in statins production, let alone a suggestion to select a culture medium comprising 50% by weight of soy ingredients selected from the group consisting of whole soybeans, crushed whole soybeans, soy protein, soy milk and soy flakes to achieve acceptable color.

(*Id.* at 16.)

### ISSUE

Has the Examiner set forth a prima face case that it would have been obvious to ferment a substrate comprising more than 50% by weight of soy ingredients with a statins producing *monascus ruber* fungus?

### FINDINGS OF FACT

FF1. Manzoni 1999 discloses that several *Monascus* strains, including *M. ruber*, were screened for statins production (Manzoni 1999, p. 253 (Abstract) & p. 254 (Materials and methods)).

FF2. In particular, Manzoni 1999 discloses:

[F]ermentation experiments were carried out employing *Monascus* . . . strains on a base medium where glucose was partially replaced with glycerol which has been found to improve lovastatin production, and whole or defatted soybean flour as the complex ingredient. . . . The aim of the investigation was to evaluate the effect of the lipid fraction as the additional carbon source in statins biosynthesis.

(*Id.* at p. 255.)

FF3. In addition, Manzoni 1999 discloses that “[s]tatins production was carried out in 750 ml Erlenmeyer flasks, containing 100 ml of the previously reported medium (Manzoni . . . 1998)[, t]he medium [being]

supplemented with 3% of whole or defatted soybean flour” (*id.* at p. 254 (Materials and methods)).

FF4. Manzoni 1998,<sup>5</sup> which is identified in Manzoni 1999 as describing the medium (FF3), discloses a “medium of the following composition (g/l): glycerol 70, peptone 8,  $\text{MgSO}_4 \cdot 7\text{H}_2\text{O}$  1, glucose 30[,] . . . supplemented with 30 g whole or defatted soybean flour/l” (Manzoni 1998, p. 529 (Materials and methods)).

FF5. Zhang discloses “a product of the fermentation of at least one *Monascus st[r]ain* that can be used as a dietary supplement or as a therapeutic medicament to lower both serum cholesterol and triglyceride levels in humans” (Zhang, col. 4, ll. 6-9).

FF6. Zhang also discloses

For all of the media preparations rice or another grain is used as a carbon source. The carbon source can be rice . . . , millet, barley, wheat, or corn. Additionally sugar and substances containing sugar can be used. Organic compounds such as glycerine and glyceride can also be used in the media preparations. . . . The culture media’s key feature is that the carbon source is selected from the group consisting of cereals, sugar, and organic compounds, the source of nitrogen is selected [from] the group consisting of beans (e.g. soya bean powder, pressed soybean cake). . . .

(*Id.* at col. 7, ll. 4-18.)

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<sup>5</sup> Matilde Manzoni et al., *Production and purification of statins from Aspergillus terreus strains*, 12 BIOTECHNOLOGY TECHNIQUES 529-532 (1998) (of record).

FF7. As an example, Zhang discloses adding 15 g of soya-bean powder and 50 ml of culture fluid “to each 100 g of polished round-grained nonglutinous rice” (*id.* at col. 12, l. 66, to col. 13, l. 1).

FF8. In another example, Zhang discloses adding “5-20% of soya-bean cake powder and 80 ml of culture fluid . . . to each 100 g of millet” (*id.* at col. 13, ll. 48-50).

### PRINCIPLES OF LAW

A claim “composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). The relevant question is “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.” *Id.*

However, “where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456 (CCPA 1955).

### ANALYSIS

The Examiner acknowledges that Manzoni 1999 “do[es] not teach a process of making a food product comprising an extract of the product obtained from fermenting a substrate comprising more than 50% by weight of soy ingredients” (Ans. 5). However, citing *In re Aller*, the Examiner finds:

[I]t is normal practice to change concentration to increase the degree of results obtained. Therefore, increase in the amount of soybean flour would increase statins production. Hence, one would have been motivated to manipulate ranges during routine experimentation to discover the optimum or workable range since Manzoni [1999] provides the general range. Therefore,

one would have been motivated to use the appropriate amount of soy ingredients.

(*Id.* at. 5-6.) We do not agree that the Examiner has set forth a prima facie case of obviousness.

Manzoni 1999 discloses a medium including glucose and glycerol, as well as soybean flour as an “additional carbon source” (FF2-4). In particular, Manzoni discloses a medium containing only 3% soybean flour (FF3). Similarly, Zhang discloses a medium including “rice or another grain . . . as a carbon source” and a relatively small amount of soya bean as a nitrogen source (FF6-8). The Examiner has not pointed to any teaching indicating that increasing the amount of soy, relative to the amount of other components in the media, would increase statins production. In addition, we do not agree that increasing the amount of soy to 50% by weight of the substrate would be considered routine optimization.

### CONCLUSION

The Examiner has not set forth a prima face case that it would have been obvious to ferment a substrate comprising more than 50% by weight of soy ingredients with a statins producing *monascus ruber* fungus. We therefore reverse the obviousness rejections of claim 19 and of claims 11-16, 20-24, and 27-29, which depend from claim 19.

REVERSED



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Application 10/072,570

cdc

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